OCT 1 0 2003

Fukuda Denshi DS-7100 Series
Special 510(k): Device Modification

Exhibit B
510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR part 870.92.

The assigned 510(k) number is: K032290.

Submitter: Fukuda Denshi U.S.A. INC.
17725 NE 65th St. Building C
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- **Contact Person:** Larry Walker
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  Fukuda Denshi U.S.A. INC.
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- **Date Prepared:** **September 30, 2003**

Device Name:

- **Proprietary Name:** Fukuda Denshi DYNASCOPE model DS-7100 Series Portable Patient Monitor
- **Common Name** Portable Patient Monitor

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- **Classification** 74 DSI - Arrhythmia Detector and Alarm - Class III

Legally Marketed Device: Fukuda Denshi model DS-5100E Portable Patient Monitor (**K971131**)

In addition several functions of the DS-7100 series Portable Patient Monitor utilizes technology incorporated into previously cleared devices and several OEM manufactured modules that have received separate clearance from the FDA as follows:

The telemetry technology is the same as that cleared for use with the DS-5100E under the Fukuda Denshi DS-5000 series telemetry (model HLX-501) cleared under 510(k) # **K980728**

The DS-LAN II technology was previously cleared in the Fukuda Denshi DS-5800 submission. **K970585.**

The Central Station Monitors the DS-7100 series can be connected were cleared under 510(k) # **K K970585, K000746** and **K020084**

The SpO_2 measurement system used in the DS-7100 series is the same as that used in the Nellcor Puritian Bennet model N-595 cleared under 510(k) # **K012891**

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Description:

The DS-7100 Series Patient Monitor is a pre-configured monitor meant to acquire and monitor physiological signals from patients. The system is design to be used in ICU, CCU, OR or recovery areas of the hospital or clinic. An optional Battery Pack Operation allows the DS-7100 series to be used to monitor patients during intra-hospital transport. Patient ages from neonates to adults can all be monitored. Waveforms, numeric and trend data from these patients are available to the clinician on the systems display or may be printed on the systems recorder.

The DS-7100 series consist of two models. The base model DS-7010L allows for the monitoring of ECG, RESP, SpO2, BP NIBP and Temp. Model DS-7101LT offers all the monitoring features of the base model and adds an integrated WMTS 600 MHz telemetry transmitter, which uses the same basic design and control mechanism which was previously cleared, for use with the predicate device, as the Fukuda Denshi DS-5000 series telemetry model HLX-501 **(K980728)**.

The DS-7100 series are self contained monitors which include an 8.4 inch TFT color LCD display which can display up to 6 waveforms. All input operation is performed on the monitors touch screen controls. Additional standard features include an Ethernet LAN for connection to Fukuda Denshi Central Stations, a built- in dot matrix thermal printer that can print up to 3 wave forms simultaneously and an alarm pole feature on the top of device that alerts to alarm conditions through 9 corresponding flashing patterns.

The device is small and lightweight at 5.2 kg. The physical dimensions of the device are 260mm (W) x 264 mm (H) x 196 mm (D). Because there is no need for a cooling fan operation is extremely quite. The AC power supply includes the battery charger for the optional battery operation to allow intra-hospital transport of patients. Use of low power, high speed flash memory allows for easy software upgrades though a standard PMCIA compatible IC card.

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Statement of Intended Use:

The Fukuda Denshi model DS-7100 series Patient Monitors provide a Simple and reliable method to display and document the continuous hemodynamic, cardiovascular observations that typically required of critically ill patients. These patients; neonate, pediatric and adult; may be located in a hospitals ICU, CCU, OR, ER, recovery or other critical care area. The DS-7100 series monitor can also be used to follow patients whose treatment requires close observation of specific physiological parameters. These patients may be in a clinic or other healthcare environment under the care of a physician.

Battery operation allows the patients to continue to be monitored during intra-hospital transport. The availability of DS-LAN II connection or Multi-parameter telemetry allows remote monitoring when combined with Fukuda Denshi Central Station Monitors.

Parameters such as ECG, respiration, non-invasive or invasive blood pressure, temperature and pulse oximetry may be monitored individually or in any grouping required by the clinician.

The Fukuda Denshi DS-7100 series Patient Monitor is not recommended for home use, during transport other than intra-hospital or when it has not been ordered by a physician.

Technological Characteristics:

The DS-7100 series incorporates the same fundamental technology as the predicate devices. Each system provides a means with interfacing with a patient, collecting parameter specific physiological data and processing the data for alarm generation, display of numeric values and waveforms at bedside or at a central monitoring station.

The technology characteristics of the DS-7100 series do not affect the safety or efficacy of the device. Any safety issues raised by a software control medical device are either the same issues already addressed by the predicate devices or are addressed the system hazard analysis, or in the system validation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2003

Fukuda Denshi U.S.A. Inc.
c/o Mr. Larry D. Walker
Regulatory Affairs Manager
17725 NE 65th Street
Redmond, WA 98052

Re: K032290
Trade Name: DS-7100 Portable Patient Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detector and alarm)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: September 10, 2003
Received: September 11, 2003

Dear Mr. Walker:

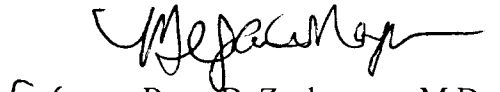
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K032290

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Exhibit E
Indications for Use

510(k) Number if Known	
Device Name	Fukuda Denshi model DS-7100 series Portable Patient Monitor
Indication for Use	Use of the Fukuda Denshi Model DS-7100 series Portable Patient Monitor is indicated in those situations where observation of one or more of the following parameters on an individual patient may be required. ECG (waveform, heart rate, ST-Level and ventricular arrhythmias), respiration, non-invasive and or invasive blood pressure, temperature and pulse oximetry. These observations can include an audible and visual alarm if any of these parameters exceed values that are established by the clinician. The observations may include the individual or comparative trending of one or more of these parameters over a period of up to 24 hours. The DS-7100 series is indicated in situations where an instantaneous display of waveform, numeric and trended values is desired. The DS-7100 is also indicated where a hard copy record of the physiological parameters, the alarmed conditions or the trended values may be required.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032290